EXHIBIT A

SUM-100

SUMMONS
(CITACION JUDICIAL)

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

ENDORSED
FILED
ALAMEDA COUNTY
OCT 26 2018
CLERK OF THE SUPERIOR COURT
By TANIA PIERCE Deputy

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

BAYER CORP., an Indiana corporation doing business in California;
(SEE ADDITIONAL PARTIES ATTACHMENT

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

KATIE ARTINIAN, an individual
(SEE ADDITIONAL PARTIES ATTACHMENT)

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.
¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

The name and address of the court is:
(El nombre y dirección de la corte es): Alameda County Superior Court
Rene C. Davidson Courthouse
1225 Fallon Street, Oakland, California 94612

CASE NUMBER:
(Número del Caso): RG18926258

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Mark P. Robinson, Jr., ROBINSON CALCAGNIE, INC. 19 Corporate Plaza Drive, Newport Beach, CA
(949) 720-1288

DATE: *(Fecha)* OCT 26 2018 Chad Finke Clerk, by *(Secretario)* TANIA PIERCE, Deputy *(Adjunto)*

(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citatión use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☒ on behalf of *(specify):* Bayer Corp, an Indiana corporation doing business in California
   under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☐ by personal delivery on *(date):*

INSTRUCTIONS FOR USE

- This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties *(Check only one box. Use a separate page for each type of party.)*:

☑ Plaintiff ☐ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

AMBER MAHONEY, an individual;
CRYSTAL TIDMORE, an individual;
IESHA ROUSE, an individual; and
CANDIDA BAHNMAIER, an individual

INSTRUCTIONS FOR USE

- This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties *(Check only one box. Use a separate page for each type of party.)*:

☐ Plaintiff ☑ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

BAYER HEALTHCARE LLC, a Delaware company doing business in California;

CONCEPTUS, INC., a Delaware corporation with its principal place of business in California, now known as BAYER ESSURE, INC.;

BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation doing business in California; and

DOES 1 through 100,

Mark P. Robinson, Jr., Esq. Bar # 054426
Karen L. Karavatos, Esq., Bar # 131718
Cynthia Garber, Esq., Bar # 208922
ROBINSON CALCAGNIE, Inc.
19 Corporate Plaza Drive
Newport Beach, CA 92660
949-720-1288; Fax 949-720-1292

Attorneys for Plaintiffs

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA - UNLIMITED JURISDICTION

KATIE ARTINIAN, an individual; AMBER MAHONEY, an individual; CRYSTAL TIDMORE, an individual; IESHA ROUSE, an individual; and CANDIDA BAHNMAIER, an individual.

Plaintiffs

v.

BAYER CORP., an Indiana corporation doing business in California; BAYER HEALTHCARE LLC, a Delaware company doing business in California; CONCEPTUS, INC., a Delaware corporation with its principal place of business in California, now known as BAYER ESSURE, INC.; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation doing business in California; and DOES 1 through 100,

Defendants

Case No. RG18926258

COMPLAINT FOR DAMAGES; DEMAND FOR JURY TRIAL

1. Negligence
2. Strict Products Liability
3. Concealment
4. Intentional Misrepresentation
5. Negligent Misrepresentation
6. Breach of Express Warranty
7. Manufacturing Defect

COME NOW Plaintiffs, and file this Complaint seeking judgment against Defendants BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC. (formerly known as CONCEPTUS, INC., a Delaware corporation with its principal place of business in California); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1 through 100, inclusive, (hereinafter collectively referred to as "Defendants" or "Bayer") for personal injuries suffered as a result of being implanted with the defective and unreasonably dangerous product, Essure®. At all times relevant

hereto, Essure® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Defendants.

I. INTRODUCTION

1. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

2. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the U.S. Food and Drug Administration ("FDA"), and thereby to the healthcare community and to consumers. The manufacturer also must carefully monitor its own quality controls post-market to ensure that the device uniformly conforms with its representations and warranties and with specifications of approval.

3. When monitoring and reporting the post-market experience with its product, including any adverse events as required by both federal regulations and state law, including California law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could mean that researchers, regulatory bodies, and the medical community are years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experience, but it must also report the data to the FDA as soon as it is received, take appropriate actions to identify the root cause of product failures, and take corrective and preventative actions as appropriate.

4. This action arises from Defendants' failure to uphold their post-market responsibilities to warn about serious health risks that became apparent to the manufacturer after their permanent birth control device, Essure®, was marketed in the United States. In 2002, the FDA approved the device for sale in the United States based on clinical studies of only 745 women presented by the device

manufacturer.

5. After the FDA approved the Essure device for sale and it began to be implanted in patients in a real-world setting, Defendants became aware of serious issues and adverse events that should have led Defendants to, among other things, report the adverse events to the FDA pursuant to 21 C.F.R. §803, et seq. For example, Defendants failed to disclose to health care providers and consumers that they had received thousands of complaints of serious injuries associated with Essure® after the device was approved for sale. The FDA was not made aware that the device could cause serious health risks, such as perforation of the uterus or fallopian tubes, device migration or fracture, chronic pain, prolonged bleeding, and unintended pregnancies. The FDA was also not made aware that the frequency and severity of complications was greater than expected, and ultimately the device must be removed requiring major surgery.

6. Defendants failed to timely report this new information to the FDA. When the FDA later became aware of this information, it made Essure a restricted device and required additional warnings, including a black box warning and Patient Decision Checklist, to reflect serious health risks that were ultimately suffered by Plaintiffs. If the Defendants had timely and adequately disclosed this information and had reported serious adverse events to the FDA, Plaintiffs' injuries would have been avoided.

7. Despite their actual knowledge about the frequency, severity, and permanence of the clinical complications associated with Essure®, Defendants persisted in conducting a nationwide false and misleading marketing campaign. In Defendants' own words, their marketing strategy aimed to capitalize on a physicians' position of trust with patients.

8. The conduct of Defendants violated their obligations under relevant federal and state law, including California law, governing the post-market conduct of Class III medical device manufacturers.

II. PARTIES, JURISDICTION AND VENUE

9. The Court has personal jurisdiction over Defendants. Defendant Bayer Essure® Inc. (f/k/a Conceptus, Inc.) and Bayer HealthCare LLC have at all relevant times maintained their corporate headquarters in, and purposefully availed themselves of the benefits, profits and privileges deriving from their business activities in the state of California. At the time of each Plaintiff's implant, all Defendants centralized Essure®'s research and development, labeling, regulatory, manufacturing, and

marketing strategy in California, and each Defendant participated in that joint effort. The Essure® devices sold to California and non-California residents were part of a common course of distribution from California; the Essure device was conceived of, tested, manufactured, packaged, approved, marketed, distributed, and sold directly from California to the 50 states and overseas. Clinical trials which formed the basis of the approval of this device were conducted from California, including facilities in Santa Clara County. Neither the product design nor the deceptive representations and omissions made about the devices differed from state to state.

10. Venue is proper in this county in accordance with the California Code of Civil Procedure because Plaintiffs in this action are asserting claims for damages and injuries arising out of Essure® products manufactured by Defendants and this case is eligible for inclusion in the statewide coordination of similar cases pursuant to sections 404, et seq., of the California Code of Civil Procedure, designated as Judicial Council Coordination Proceeding No. 4887, titled *Essure Product Cases*. This case will be the subject of a Petition for Coordination of Add-On Cases ("Add-On Petition") as coordinating this case with JCCP No. 4887 before one judge for all pretrial purposes will promote the ends of justice, as required by sections 404.1 and 404.4 of the California Code of Civil Procedure. Joining Plaintiffs together in this action is proper pursuant to section 378 of the California Code of Civil Procedure because all Plaintiffs assert rights arising out of the same transaction, occurrence, or series of transactions or occurrences and questions of law or fact common to all Plaintiffs named herein will arise in the action.

11. At all relevant times alleged herein, Plaintiff KATIE ARTINIAN, a competent individual, and over the age of 18, was a citizen and resident of the State of California, Orange County, and the injuries alleged herein arose out of conduct that occurred in this state and/or this county.

12. At all relevant times alleged herein, Plaintiff AMBER MAHONEY, was and is a competent individual, and over the age of 18. Said Plaintiff is currently a resident and citizen of Scott County, Iowa.

13. At all relevant times alleged herein, Plaintiff CRYSTAL TIDMORE was and is a competent individual, and over the age of 18. Said Plaintiff is currently a resident and citizen of Madison County, Alabama.

14. At all relevant times alleged herein, Plaintiff IESHA ROUSE was and is a competent individual, and over the age of 18. Said Plaintiff is currently a resident and citizen of Wayne County, Michigan.

15. At all relevant times alleged herein, Plaintiff CANDIDA BAHNMAIER was and is a competent individual, and over the age of 18. Said Plaintiff is currently a resident and citizen of Lane County, Oregon.

16. Defendant BAYER CORP. is a for-profit corporation incorporated in the state of Indiana with its principal place of business in Pennsylvania. Bayer Corp. indirectly owns both Bayer Essure, Inc., which is one of the members of Bayer Healthcare, LLC, and Bayer Healthcare Pharmaceuticals, Inc. Bayer Corp. presently and in the past has simultaneously shared officers, agents, and/or employees with Bayer Healthcare, LLC, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Essure, Inc. (f/k/a Conceptus). Bayer Corp. also provided support for Bayer's acquisition of Bayer Essure, Inc. (f/k/a Conceptus) and it is the custodian of documents related to the acquisition. Bayer Corp. maintains offices in Commerce, San Ramon, Fresno, Chula Vista, Mission Viejo, and Long Beach, California. Bayer Corp.'s U.S. Innovation Center, a 48-acre Multipurpose Biotechnology Plant, is located in Berkeley, California. At all relevant times, Bayer Corp. engaged in conduct in California, together with Bayer Healthcare Pharmaceuticals, Bayer Healthcare, LLC, and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs.

17. Defendant BAYER HEALTHCARE LLC is a for-profit limited liability company organized under the laws of the state of Delaware with its principal place of business in Pennsylvania. It is a wholly owned subsidiary of Bayer A.G. Bayer Healthcare, LLC's sole member is Defendant Bayer Corp. Bayer Healthcare, LLC is authorized to and does business throughout the state of California and during the time period relevant to this litigation had manufacturing operations located in Berkeley, Alameda County, California and research and development operations in San Francisco, San Francisco County, California. At all relevant times, Bayer Healthcare, LLC's principle place of business for its Essure® operations, including, but not limited to, Quality Assurance through which technical and

medical complaints were processed, was in a plant in Milpitas, California, which is the same plant from which Conceptus performed Essure® functions. At present, Bayer Healthcare, LLC maintains facilities in Berkeley, California and corresponds with the FDA regarding Essure® from this location. At all relevant times, Bayer Healthcare, LLC engaged in conduct in California, in concert with Bayer Healthcare Pharmaceuticals, Bayer Corp., and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs. At all times relevant to this action, Bayer Essure, Inc. and Bayer Healthcare LLC, both California entities, acted as agents for Bayer Corp. in the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States.

18. Defendant BAYER ESSURE® INC. (F/K/A CONCEPTUS, INC.) is a for-profit corporation incorporated in the state of Delaware and is a wholly owned by subsidiary of Bayer A.G. and/or Bayer Healthcare, LLC. Conceptus, Inc. ("Conceptus") was a Silicon Valley "start up", founded in 1992 by Julian Nikolchev, a self-described "medical technology developer and serial entrepreneur." On or about April 28, 2013, Conceptus, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Bayer HealthCare LLC. On or about June 5, 2013, pursuant to the Merger Agreement, Conceptus, Inc. became a wholly owned subsidiary of Bayer HealthCare LLC and, thereafter was renamed "Bayer Essure Inc." For purposes of this Complaint, Conceptus, Inc. and Bayer Essure Inc. are one and the same. Bayer Essure Inc.'s headquarters were located at 1021 Howard Avenue, San Carlos, California 94070, until 2005 when they relocated to 331 East Evelyn Avenue, Mountain View, California 94041. In July of 2013, Bayer Essure Inc. moved its headquarters to 1011 McCarthy Boulevard, Milpitas, Santa Clara County, California 95035. On or about July 1, 2013, Bayer Healthcare LLC and Conceptus entered into an Asset Sale Agreement, whereby Conceptus agreed to transfer substantially all of its operating tangible assets and certain liabilities to Bayer Healthcare LLC. That same day, Conceptus assigned its lease of the Milpitas facility, from which it was conducting substantially all of its Essure® functions, to Bayer Healthcare LLC. Thereafter, Bayer Healthcare LLC was the lessee and occupant of the premises and performed its Essure functions from the premises at

least until March 2016 or later. In July 2015, Bayer Essure, Inc. transferred its remaining assets and liabilities (except certain tax assets and liabilities) to Bayer Healthcare LLC in exchange for common membership units in Bayer Healthcare LLC. Upon information and belief, as of May 20, 2016, Bayer Essure Inc. surrendered its right to conduct intra-state business in the state of California. In its 2017 Annual Report, Bayer AG listed Bayer Essure, Inc. as a fully consolidated subsidiary with a place of business in Milpitas, California. Bayer Essure, Inc. played a primary role in Essure®-related operations, such as manufacturing, marketing, promotion, product labeling, and regulatory affairs. At all times relevant hereto, Bayer Essure engaged in conduct in California, in concert with Bayer Healthcare Pharmaceuticals, Bayer Healthcare, LLC, and Bayer Corp., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure throughout the United States, including the Essure® devices implanted in Plaintiffs. At all times relevant to this action, Bayer Essure, Inc. and Bayer Healthcare LLC, both California entities, acted as agents for Bayer Corp. in the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States.

19. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of Delaware and is a wholly owned subsidiary of Bayer A.G. Bayer Healthcare Pharmaceuticals. It is authorized to and does business throughout the state of California. Bayer Healthcare Pharmaceuticals, played a role in the marketing, promotion, product labeling, and post-market surveillance for Essure®. Bayer Healthcare Pharmaceuticals, Inc. maintains offices in San Pablo, Emeryville, and San Diego and employs roughly 500 employees in California. At all relevant times, Bayer Healthcare Pharmaceuticals, Inc. engaged in conduct in California, together with Bayer Corp., Bayer Healthcare, LLC, and Bayer Essure, Inc., concerning the design, research, development, manufacturing, testing, packaging, promotion, marketing, distribution, labeling, dissemination and/or sales of Essure® throughout the United States, including the Essure® devices implanted in Plaintiffs.

20. In as early as 2004, the Defendants began sub-contracting the manufacture and sterilization of the device to several other companies, including Accellent Corp., f/k/a Venusa, Ltd., Accellent Inc.

d/b/a Lake Region Medical Inc., FlexMedical, formerly named Avail Medical, and Sterigenics International. Defendants are liable for the actions and inactions of these sub-contractors.

21. At all times herein mentioned, there existed a unity of interest, and activity in furtherance of that interest, among Defendants such that any individuality and separateness among them has ceased, and these Defendants are the alter egos of each other with respect to Essure® operations.

22. Defendants acted jointly and in combination with one another to take advantage of each Defendants' resources, personnel, services, and sales, marketing and promotional networks. This includes the Defendants transacting, soliciting and conducting business in California through their offices, employees, agents and/or sales representatives, from which they derived substantial revenue in California.

23. At all times herein mentioned, Defendants, jointly and individually, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling the Essure® device. These products were for use by Plaintiffs and Plaintiffs' physicians and were implanted into Plaintiffs in the same condition as when the Essure® devices left Defendants' control. As such, each of the Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

24. The true names and capacities of those defendants designated as DOES 1-100, whether individual, corporate, association or otherwise, are unknown to Plaintiffs at the time of filing this Complaint and Plaintiffs, therefore, sue said defendants by such fictitious names and will ask leave of Court to amend this Complaint to show their true names or capacities when the same have been ascertained. Plaintiffs are informed and believe, and thereon allege, that each of the DOE defendants is, in some manner, responsible for the events and happenings herein set forth and proximately and/or directly caused injury and damages to Plaintiffs as herein alleged.

III. DESCRIPTION OF ESSURE®

25. Essure® is a medical device manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold

by Defendants.

26. Essure® was first manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by Conceptus, Inc. and initially developed under the name Selective Tubal Occlusion Procedure or "STOP™" Permanent Contraception device.

27. Essure® is touted as a form of permanent female birth control (female sterilization) with a 99.3% effectiveness rate of preventing pregnancy. Defendants intended the device to be implanted "permanently," *i.e.*, to remain securely in place for each patient's lifetime.

28. Essure® consists of three components: (1) two micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use.

29. The micro-inserts are composed of two metal coils: one coil made of nitinol (nickel and titanium) and the other made of steel with polyethylene terephthalate ("PET") fibers wound in and around the coil. The micro-inserts are inserted through the vagina, cervix, and uterus and then implanted into a woman's fallopian tubes via Defendants' disposable delivery system.

30. Defendants' disposable delivery system consists of a single handle that contains a nitinol core delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians monitor this process through hysteroscopic equipment, including a hysteroscope, a lightbox, and a monitor, collectively known as a "tower."

31. The hysteroscopic equipment is not part of the Essure® device or its pre-market approval process, but the equipment is necessary for proper implantation of the Essure® device.

32. After implantation of the coils in the fallopian tubes, the micro-inserts are intended to expand and cause a chronic inflammatory and fibrotic response to the PET fibers which elicits tissue growth that blocks the fallopian tubes and prevents pregnancy.

33. The Instructions for Use ("IFU") accompanying the Essure® device provide that patients should be counseled to receive a confirmation test three months post-implant to determine that there is complete occlusion in each fallopian tube. The Confirmation Test is performed using a hysterosalpingogram ("HSG Test") and, as of July 2015, a transvaginal ultrasound ("TVU").

34. Since Essure®'s market entry in 2002, the device has undergone several design changes. The Selective Tubal Occlusion Product ("STOP") device was the original model used in the two clinical trials (STOP 10 and STOP2000) submitted in an effort to obtain FDA approval of the device. The first U.S. launched device was the ESS205 model, which was comprised of the same coil insert as the STOP device, but incorporated a different delivery system (i.e., support catheter). The original support catheter was discontinued in 2003 to address continued reports of difficulty/failure to disengage or detach the delivery wire from the Essure micro-insert during implantation. Additional changes were later made to the delivery system. In 2007, Defendants changed the shape of the inserts by removing the tapered "pigtail" at the proximal end of the outer coil and renamed the device the ESS305 model.

IV. PRE-MARKET APPROVAL AND POST MARKET OBLIGATIONS

35. In April 2002, Conceptus submitted its Premarket Approval Application to the FDA for the Essure® device.

36. Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices based on the information available at the time. *See* 21 U.S.C. § 360(e); 21 C.F.R. § 814.3(e).

37. On November 4, 2002, the FDA conditionally approved the Essure® PMA application to market the device in the United States.

38. FDA approval in 2002 was based on studies of only 745 clinical trial patients for a short period of time; the majority of the clinical trial data regarding the coils and PET in the fallopian tube was based on only 12–24 months of implantation. Beyond 24 months, therefore, the nature of the body's cellular and fibrotic response to the inserts and the ability of the devices to maintain occlusion were unknown. The FDA advised Conceptus of these facts and emphasized their special significance with respect to the risk of ectopic pregnancies, putting Conceptus on clear notice that the company's duty to vigilantly monitor and report the real world clinical experience with the device was paramount. Thus, the importance of maintaining the integrity of post-marketing data collection and reporting was known to Defendants from the outset.

39. Approval of a device through the PMA process signals the beginning, not the end, of a

device manufacturer's duties to patients under both federal regulations and established state law, including California law. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval as new safety information from the real-world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are products, such as Essure®, for which evidence of the device's defects comes to light only after the device is used in a real-world setting.

40. The FDA's Conditional Premarket Approval ("CPMA") Order for Essure® outlined several requirements for the manufacturer, and the CPMA expressly made non-compliance with any of these requirements a violation of federal law. For example, the Order required that the manufacturer:

a. conduct a post-approval study in order to gather long-term safety and effectiveness data on Essure®;

b. conduct a post-approval study in the U.S. to "document the bilateral placement rate [of Essure®] for newly trained physicians";

c. annually report on the patients who participated in the post-approval studies;

d. ensure that any warranty statements are truthful, accurate, not misleading and are consistent with applicable federal and state laws;

e. submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification;

f. submit pursuant to 21 CFR §814.84 a post-approval Annual Report that includes 1) a bibliography and summary of information from unpublished reports of data from any clinical investigations or non-clinical laboratory studies involving Essure® as well as reports in the scientific literature concerning Essure®, 2) identification of changes made pursuant to §814.39(a) or (b) that effect the safety or effectiveness of the device, and 3) any failures of the device to meet the specifications established in the approved PMA that were correctable by procedures described in the

approved labeling;

g. submit pursuant to 21 CFR §814.82(a)(9) a "Device Defect Report" or "Adverse Reaction Report" to the FDA within 10 days after Defendants receive or have knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has either not been addressed by the device's labeling, or has been addressed by the device's labeling but is occurring with unexpected severity or frequency. The express purpose of this requirement is to provide continued reasonable assurance of the safety and effectiveness of the device;

h. submit pursuant to 21 CFR §814.82(a)(9) a "Device Defect Report" or "Adverse Reaction Report" to the FDA within 10 days after Defendants receive or have knowledge or information of any significant change or deterioration of the device, or any failure of the device to meet specifications established in the approved PMA, that could not cause or contribute to death or serious injury, but is not correctable by adjustments or other procedures described in the approved labeling. The express purpose of this requirement is to provide continued reasonable assurance of the safety and effectiveness of the device;

41. The CPMA Order for Essure® further outlined reporting requirements that Defendants were required to follow under the Medical Device Reporting regulations ("MDR"). Under these requirements, pursuant to 21 CFR §803.50, et seq. Defendants were required to:

a. Report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury. *See* 21 CFR 803.50(a)(1);

b. Report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur. *See* 21 CFR 803.50(a)(2);

c. Report to the FDA within 5 days after Defendants received or became aware that a reportable MDR event requires remedial action to prevent an

unreasonable risk of substantial harm to the public health. *See* 21 C.F.R. § 803.52; and,

d. Report to the FDA within 30 days after Defendants received any supplemental information that was not provided in the initial report. *See* 21 C.F.R. §803.56.

42. The CPMA Order acknowledged the Defendants' obligation and ability to update safety warnings for Essure® without prior FDA approval by utilizing the "Changes Being Effected" provision in 21 C.F.R. § 814.39(d)(2).

43. The FDA made clear in the CPMA order that "[f]ailure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Act."

44. In order to comply with its reporting obligations under the Essure® CPMA and federal law, Defendants were required to conduct an investigation of each adverse event and evaluate the cause of the event. *See* 21 C.F.R. §§ 803.50(a); 803.50(b)(3)

45. To competently investigate whether a complaint represents an adverse event required to be reported under §803.50 et seq., Defendants were required to establish and maintain procedures for receiving, reviewing, and evaluating complaints of adverse events by a formally designated unit to ensure that 1) all complaints were processed in a uniform and timely manner; 2) oral complaints were documented upon receipt; and 3) complaints were evaluated to determine whether the complaint represents an adverse event which is required to be reported to the FDA. *See* 21 CFR §§803.17; 820.198(a).

46. Any complaint involving the possible failure of a device to meet any of its specifications must be reviewed, evaluated, and investigated; and records of these complaints must be maintained separately. 21 CFR §820.198(d). If a manufacturer decides not to investigate a complaint, they must maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. *See* 21 CFR §820.198(b).

47. Whether or not the manufacturer determines the event is an MDR reportable event, they must maintain a MDR file that contains all information and documentation in their possession related

to the adverse event, a record of any investigation and the results of any evaluation of an adverse event, any information a qualified person used to determine whether or not a device-related event was reportable, copies of all reports submitted to the FDA related to the adverse event, and copies of all electronic acknowledgements the FDA sends in response to an MDR submission. *See* 21 CFR §§803.18(a); 803.18(e); 803.20(c)(2); 803.22(b)(1); 820.198(e) et seq.

48. If a manufacturer fails to adequately and timely evaluate and investigate reports of adverse events pursuant to the FDCA, it is impossible for the manufacturer to comply with its reporting requirements under the same.

49. The FDCA states, "If you are a manufacturer...you must report deaths and serious injuries that your device has or may have caused or contributed to, and you must also submit specified [follow up.] These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use."

50. The FDCA requires medical device manufacturers like Defendants to maintain and submit information as required by FDA regulations as described above. The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety data on medical devices. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

51. Upon information and belief, Defendants failed to establish and maintain procedures for receiving, reviewing, and evaluating complaints of adverse events, they failed to timely and adequately evaluate and investigate complaints of adverse events, and failed to timely report complaints of adverse events to the FDA. These failures violated regulations outlined above under federal law and subsequently violated state law.

52. Had Defendants fulfilled their post-market reporting obligations in a timely fashion, which federal and state law required them to do, Plaintiffs' injuries would not have occurred.

53. Pursuant to 21 U.S. Code § 352 (m), a medical device is rendered misbranded if its advertising is false or misleading in any particular.

54. Additionally, in the case of any restricted device distributed or offered for sale in any State,

such a device is rendered misbranded unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device, a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

55. Pursuant to 21 U.S. Code § 321 (n), if an article is alleged to be misbranded because the advertising is misleading, then in determining whether the advertising is misleading, there shall be taken into account (among other things), not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the advertising relates under the conditions of use prescribed in the advertising thereof or under such conditions of use as are customary or usual.

56. Defendants' concealment of adverse events, health hazards, and risks associated with Essure® rendered the Essure® device misbranded.

57. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

58. By failing to ensure representations regarding Essure® were truthful, accurate, and not misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

V. DEFENDANTS BREACHED THEIR OBLIGATION TO UPDATE WARNINGS AND REPORT ADVERSE EVENTS

59. The claims in this case concern Defendants' duties that arose after premarket approval of Essure®, when Defendants learned of new information bearing on the safety of its device. Defendants' systemic noncompliance with federal regulations can be seen throughout the company's history as they continuously failed to acknowledge, report, correct, and warn about known problems with the Essure® device. This neglect contributed to thousands of adverse events in women implanted with Essure®. Defendants' subsequent failure to report these adverse events and update warnings is part and parcel of Defendants' indifferent attitude toward federal regulations and their CPMA.

60. Under state law, including California law, Defendants had a duty to exercise reasonable care in adequately warning about the dangers of Essure® that were known or knowable to Defendants at the time of distribution. Under both federal and state law, Defendants have a post-market duty to report adverse events and risks associated with the device.

61. Despite having knowledge and possession of evidence that showed the use of Essure® was dangerous and likely to place users' health at serious risk, Defendants failed to disclose the known or knowable health hazards and risks associated with Essure®. Defendants' conduct here failed to meet their federal obligations and violated state law, including California law.

62. Throughout its existence, Conceptus accumulated hundreds of millions of dollars of debt and never achieved profitability.

63. By 2007, Essure® was the only product sold by Conceptus, and Defendants had greatly increased production and sales of the device.

64. Upon information and belief, as their sales volume grew, Defendants were not adequately staffed or equipped to comply with federal regulations regarding the investigation and reporting of adverse events that were continuously brought to their attention.

65. To protect the Essure® brand within the permanent birth control market, Defendants made a decision to hide their knowledge of serious safety risks from the FDA and to misrepresent the safety and efficacy of the device in its marketing materials.

66. Conceptus was aware of thousands of unreported adverse events stemming from the Essure® device. Defendants failed to take any action to correct the device failures, failed to report its knowledge of known device failures to the FDA, and failed to disclose to the medical community the increased risk of adverse events related to Essure®.

67. Some of these adverse events included perforations of the fallopian tubes, uterus, and other organs. The FDA previously advised Defendants as early as 2004 that FDA considers tubal perforations to be MDR-reportable events under 21 CFR 803 and all cases should be reported to the FDA.

68. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, if ORA investigators observe conditions they deem to be objectionable, these observations are required to be listed on an FDA Form 483 when

they indicate that an FDA-regulated product may be in violation of FDA requirements.

69. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related, non-cited objectionable conditions that exist.

70. From December 8, 2010 through January 6, 2011, the FDA conducted a fifteen-day "For Cause" inspection. During the fifteen-day "For Cause" inspection, the FDA noted conditions that it found objectionable and/or constituted violations of the FDCA and related Acts.

71. The objectionable conditions were communicated to Conceptus by the FDA via a Form 483 dated January 6, 2011, and included the:

a. failure to submit MDR Reports to the FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to death or serious injury. This included injuries that occurred during the Essure placement procedure involving the use of equipment indicated in the PMA for use during the procedure. Examples given included failure to submit MDR reports for: 1) two reports of bowel perforation, 2) one report of pain and the Essure® device breaking into pieces immediately following implant, 3) 41 complaints that involved perforation of the uterus or fallopian tubes;

b. failure to submit MDR's to the FDA within 30 days for reports of the device failing to function as specified in the PMA when it would be likely to cause or contribute to serious injury. Examples given included failure to submit MDR reports for five reports of the Essure® coils perforating the fallopian tubes and penetrating the abdominal or peritoneal cavity;

c. failure to include perforation of the Essure® micro-coil insert into the peritoneal cavity in its Design Failure Mode Effects Analysis (DFMEA) for Essure®, despite having documented at least 508 complaints of perforation involving the Essure® device;

d. and failure to adequately document in a Corrective Action and Preventative Actions ("CAPA") an incident involving Conceptus's contract manufacturer using uncertified material in a validation protocol and failing to follow their own Standard Operating Procedure for control of non-conforming material.

72. The FDA inspector specifically advised Defendants that any instances of the device migrating to, perforating, or penetrating areas in the body outside of the fallopian tubes constituted a malfunction and should be reported. In response, the Quality Manager at Conceptus told the inspector that he did not consider an Essure® device migrating out of the fallopian tube because of a perforation to be a device malfunction.

73. In their response to the FDA regarding the form 483 on January 20, 2011, Defendants "acknowledged that the Essure® device 'malfunctioned' in these cases, since the device failed to 'meet its performance specifications or otherwise perform as intended,' namely, to cause permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes."

74. The FDA Establishment Inspection Report for this inspection was issued on May 18, 2011, and stated the following:

a. All firm personnel identified Mr. Sieczkarek as the person most responsible for the company's response to the FDA investigation, which included an investigation of consumer complaint reporting violations.

b. "My inspection of the complaint system of Conceptus Inc. found that the firm was not reporting complaints of loose micro-insert coils in the peritoneal or abdomino-pelvic cavity (*See* FDA483 Observation #2). Some placement procedures have a perforation of the fallopian tubes. In some of these cases the micro-insert coil will migrate through the perforation in the tube and will be found on x-ray to be outside the female reproductive tract in the peritoneal cavity. Such cases will be reported as MDR by the firm if the patient is complaining of pain and a second procedure is required to remove the coil. However, the firm will not report such complaints if an abdominal located coil is removed during a laparoscopic tubal ligation performed because of failure of the Essure® procedure."

c. During this inspection, Conceptus gave the FDA inspector "an Excel spreadsheet with all of the complaints opened since Jan. 1, 2008 [and] there were 16,581 complaint[s] from 1/1/08 until 12/6/10 listed. There were 182 MDRs reported in the same time period."

d. Conceptus also gave the FDA inspector a more detailed complaint spreadsheet "that starts at 7/20/2010 and goes to 12/10/2010. That spreadsheet [had] a total of 2,752 complaints."

e. The FDA inspector looked at the complaints for perforation and noted that a review of these databases showed that in the previous two years there were no less than 177 complaints for perforation with migration, however "that figure may not be exact because complaints could have multiple failure modes with only one listed on the less detailed database."

f. A review of the Risk Analysis Design Failure Mode Effects Analysis showed that there is no failure mode for perforation itself or inserts migrating into the peritoneal cavity. The inspector asked if the firm had any safety data for an intraperitoneal location of the coil inserts. He could only provide anecdotal information for the Phase II clinical trials.

g. The FDA inspector told Defendants that the reason for considering complaints in which the micro-insert was found in the peritoneal cavity to be likely to lead into an injury was based on the number of MDR's in the firm's database in which such a situation led to a complication. Defendants stated that they "did not consider a micro-insert falling out of the fallopian tube because of a perforation to be a 'malfunction' because it does not involve a malfunction of the micro-insert itself." The inspector reiterated that the coil migrating to a different location represented the device not functioning as it was designed and was the condition that led to an intra-abdominal coil becoming symptomatic in all cases in which an intra-abdominal coil had to be removed surgically.

75. Defendants failed to report incidences of device malfunction and serious injury in

accordance with FDA regulations. The FDA's review of Defendants' complaint databases showed that there was an inherent flaw in the way reports of adverse events were categorized and stored.

76. On May 11, 2011, at the first quarter 2011 earnings call, Mr. Sieczkarek discussed their plan to continue to promote Essure® as safe and effective despite the thousands of adverse event reports they had received. During that call, Mr. Sieczkarek stated, "We intend to increase productivity, grow our physician pipeline, expand Essure® utilization, and drive greater patient adoption through integrated marketing." He again described Essure®'s "superior efficacy, reduced patient trauma, risk and recovery, and lower cost versus tubal ligation" to investors. He did not discuss how Conceptus had been put on notice of their violations of FDA regulations and failed to report serious adverse events to the FDA.

77. On August 4, 2011 at the second quarter earnings call, Mr. Sieczkarek stated they had a "comprehensive publication plan to keep physicians up to date on information that may impact their use of Essure®." Despite these statements, Defendants continued to underreport adverse events associated with Essure® to the FDA and medical community.

78. Defendants intentionally, willfully, and maliciously concealed and/or suppressed material safety information regarding Essure® in order to increase sales of Essure®, protect the Essure® brand, and increase market share.

79. From May 30, 2013 through June 26, 2013, the FDA conducted another inspection that included an evaluation of Defendants' complaint handling and adverse event reporting practices. As part of the inspection process, the FDA requested a complete list of complaints since January 2011. Defendants provided the FDA inspector with a spreadsheet containing 16,047 complaints Conceptus received on the Essure® device between January 2011 and the date of the inspection, only 183 of which were reported by Defendants to the FDA as MDRs.

80. The inspector reviewed 29 random complaint forms received by Defendants. None of the randomly reviewed complaints in which one or more coils were imaged outside of the fallopian tubes were reported to the FDA as MDRs.

81. Upon information and belief, from January 1, 2008 through May 2013, Defendants were receiving on average over 15 complaints per day about their product and thousands of complaints each

year. Defendants timely reported only a tiny fraction of these complaints to the FDA.

82. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations.

83. Defendants had unique knowledge concerning the frequency, severity, and permanence of the complications and risks associated with the Essure® device. Despite this unique knowledge, Defendants failed to take necessary action —such as timely submitting MDRs—to advise users of Essure® of the defects and risks described above, violating state law, including California law.

84. Defendants' actions violated the conditions of the Essure® CPMA, parallel state laws governing the post-marketing conduct of Conceptus, and FDA Regulations related to complaint handling, investigation, and reporting to the FDA, including, but not limited to, 21 C.F.R. § 803.10; 21 C.F.R. §803.17; 21 C.F.R. §803.18; 21 C.F.R. §803.20; 21 C.F.R. §803.22; 21 C.F.R. § 803.3; 21 C.F.R. §803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21 C.F.R. §803.22(b)(1); 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; and 21 C.F.R. §820.198.

85. Defendants' failure to adequately investigate complaints and to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency violated the CPMA, FDA post-marketing regulations, and parallel state law. Defendants' violations prevented Plaintiffs, their physicians, and the public from learning of Essure®'s adverse events, risks, and ineffectiveness.

86. Defendants' actions violated duties under state law, including California law, governing their post-marketing conduct.

87. The medical community, prescribing and implanting physicians, healthcare providers, and patients, including Plaintiffs and their healthcare providers, neither knew, nor had reason to know at the time of their use of Essure®, of the existence of the aforementioned adverse events and defects. Ordinary consumers would not have recognized the potential risks or side effects that Defendants concealed and misrepresented through their promotion of Essure®.

88. Only after the FDA directed Defendants to disclose the withheld information did the medical community become aware of the frequency, severity, and permanence of complications associated with the prescription and implementation of the Essure® device.

89. Between Essure®'s inception in 2002 until 2015, the FDA received approximately 9,900 medical device reports (MDRs) related to safety problems with the device. Of those 9,900 MDRs, 8,950 reports were received by the FDA between October 26, 2013 and December 31, 2015.

90. Since that time, a consulting firm specializing in medical device post-marketing surveillance, Device Events, recently analyzed data provided to the FDA by a Congressman and uncovered raw data showing discrepancies in Defendants' reporting practices, making it impossible to assess the true frequency of occurrences of the adverse events that Defendants did report.

91. For example, previously the FDA was aware of only five fetal deaths among women who had the Essure® device, but acknowledged 299 additional fetal deaths after reviewing the Device Events reports.

92. The analysis showed that the manufacturers' reports were falsely marked as mere injury or malfunction reports. However, they described instances of miscarriage, abortion or fetal death, and should have been categorized as "death" reports.

93. Defendants' conduct violated the Essure® CPMA, parallel state laws regarding post-marketing conduct, and the FDA post-marketing regulations, which ultimately prevented Plaintiff, physicians, and the public from understanding the true nature of Essure®'s adverse events, risks, and ineffectiveness.

VI. FDA REQUIRES BLACK BOX WARNING FOR ESSURE®

94. In response to continued public complaints, on September 24 and 25, 2015, the FDA convened a public hearing concerning the safety and efficacy of the Essure® device.

95. On February 29, 2016, the FDA first announced "actions to provide important information about the risks of using Essure® and to help women and their doctors be better informed of the potential complications associated with" the device. These actions included implementing a Black Box Warning and unprecedented Patient Decision Checklist.

96. On October 31, 2016, the FDA announced its Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization, stating:

> "FDA believes that some women are not receiving or understanding information regarding the risks and benefits of permanent, hysteroscopically-placed tubal implants that

are intended for sterilization. This guidance addresses these concerns by identifying labeling components, namely a boxed warning and patient decision checklist, which FDA intends to require as part of the labeling for these devices. FDA believes this will help to ensure a woman receives and understands the benefits and risks associated with her contraceptive options so that she can make an informed decision…"

97. The FDA advised that "[a]ccurate product labeling and effective messaging of that labeling is important to make device users and patients aware of the risks associated with permanent, hysteroscopically-placed tubal implants intended for sterilization. FDA believes that a boxed warning and a patient decision checklist as described in this guidance should be included."

98. The FDA took the following actions in its announcement:

a. Requiring a black box warning on Essure® to warn doctors and patients of "reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions." The FDA draft guidance black box warning for Essure® also warns: "If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System for Permanent Birth Control during discussion of the benefits and risks of the device."

b. Requiring Defendants to implement a Patient Decision Checklist to help to ensure women receive and understand information regarding the benefits and risks of Essure®. The FDA's recommended Patient Decision Checklist is a three-page single spaced document that the physician will discuss with each patient interested in using the device. The patient must initial after each topic of discussion, and both the physician and patient must sign the document. The topics for discussion include, *inter alia*, the risks for "unintended pregnancy," "the risks of Essure on a developing fetus," and increased risk for…ectopic pregnancy…may result in serious and even life-threatening complications;" "continued pain or new pain;" "some women may develop allergic reactions…and have signs or symptoms such as rash and

itching…may occur even if there is no prior history of sensitivity" and "there is no reliable test to predict ahead of time who may develop a reaction to the device;" "a sign of an Essure-related problem…might require further evaluation and treatment, including possibly the need to have the device removed by surgery;" "headaches, fatigue, weight changes, hair loss and mood changes such as depression;" "the device could poke through the wall of the uterus or fallopian tubes ("perforation") and/or move to other locations in the abdomen and pelvis ("migration");" "the device may become ineffective in preventing pregnancy and may lead to serious adverse events such as bleeding or bowel damage which may require surgery to address;" for removal "a surgical procedure will be required," including "hysterectomy (removal of the entire uterus);" and "device removal may not be covered by…insurance company.

c. Requiring Defendants "to conduct a new postmarket surveillance study designed to provide important information about the risks of the device in a real-world environment." The study must provide data on "the risks associated with Essure® and compare them to laparoscopic tubal ligation. This includes the rates of complications including unplanned pregnancy, pelvic pain and other symptoms, and surgery to remove the Essure® device. The study will also evaluate how much these complications affect a patient's quality of life. . . . The FDA will use the results of this study to determine what, if any, further actions related to Essure® are needed to protect public health."

99. On September 2, 2016 the FDA approved the post-market surveillance study plan which required a sample size of 2,800 women of childbearing age who chose to undergo either hysteroscopic sterilization with Essure® or laparoscopic tubal sterilization. The main safety endpoints of the study include evaluating; 1) chronic lower abdominal and/or pelvic pain, 2) abnormal uterine bleeding (new onset or worsening), 3) hypersensitivity and allergic reactions including autoimmune disorders or autoimmune-like reactions, and 4) invasive gynecologic surgery including Essure® insert removal. Secondary safety endpoints include other adverse events and effectiveness. This open-label, non-randomized, prospective observational cohort study will be the first clinical study to directly compare

Essure® with tubal ligation.

100. On November 22, 2016, the FDA approved final labeling with Defendants' changes in response to the FDA's guidance. The Essure® patient information booklet was updated to include:

a. A black box warning that outlined reported adverse events such as perforations of the uterus and/or fallopian tubes, migration into the abdominal cavity, and persistent pain. The black box warning also warns that if the device needs to be removed, a surgical procedure will be required.

b. A patient decision checklist.

c. Additional warnings about long-term risks including Pain (acute or persistent) of varying intensity and length of time; warnings regarding hypersensitivity to Essure® components; that removal of the device will require surgery which may include removal of fallopian tubes and/or hysterectomy; that there have been reports of pregnancy loss, pre-term labor, premature delivery, stillbirth, neonatal complications, and genetic and developmental abnormalities in pregnancies with Essure®; and that other symptoms have been reported such as headache, fatigue, weight changes, hair loss, and mood changes.

101. On March 8, 2018, FDA Commissioner Scott Gottlieb issued a statement regarding the FDA's ongoing post-market review of Essure®. He stated, "While the FDA continues to believe that Essure® may be appropriate for some women based on our current information, the agency also recognizes that serious problems have been associated with its use. We're continuing to monitor adverse events reported to our database, as well as other data sources, such as the post-marketing (522) study, and will communicate publicly on any new findings or concerns."

102. On April 9, 2018, the FDA issued an order further restricting sales of the Essure® device to only doctors and healthcare facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement." Sale and distribution of Essure® is limited to healthcare providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure® implantation. The Physician must also sign the document to verify that the warnings were given. The FDA issued this order after becoming aware that women were not being adequately informed of Essure's® risks prior to implantation. The FDA

approved this new safety measure to ensure that the device meets standards for a reasonable assurance of safety and effectiveness. Additionally, the FDA announced plans to require Defendants to increase the number of participating study sites for their post-market surveillance study to account for declining sales volume of Essure®.

103. Unfortunately, these new warnings, labeling, and patient decision checklist came too late to warn Plaintiffs of the true risks of Essure®.

104. On July 20, 2018 Bayer notified the FDA that the Essure Permanent Birth Control Device will no longer be sold or distributed in the United States after December 31, 2018. The same day, FDA Commissioner Scott Gottlieb issued a statement regarding Bayer's decision to halt sales of Essure. He stated, "The device has been associated with serious risks including persistent pain, perforation of the uterus and fallopian tubes, and migration of the coils into the pelvis or abdomen. As the FDA learned more from patients about the serious adverse events associated with this device, we took a series of important actions to better understand the benefits and risks, and to address patient safety concerns."

105. He stated that, "When we [FDA] first became aware of an increase in adverse events submitted to our database concerning this device, we launched an ongoing effort to review these reports to better understand concerns." Commissioner Gottlieb outlined the FDA's efforts regarding Essure, described above, and further stated, "Since the FDA ordered Bayer to conduct the post-market study and then to add a boxed warning and a Patient Decision Checklist to the labeling, there has been an approximate 70 percent decline in sales of Essure in the U.S. The company stated its decision to halt sales and distribution of the device was due to commercial reasons."

106. Notwithstanding Bayer's decision to remove Essure from the market, they must still meet their postmarket obligations regarding the device, including timely reporting adverse events in those who have had Essure implanted, and proceeding with the 522 post market study. "Each study participant will be followed for a total of three years and the company will continue to submit reports to the FDA on the study's progress and results."

107. Had Defendants complied with their federal regulatory duties and their duties under California law by warning about and reporting the known risks and complications in a timely fashion, Plaintiffs and their physicians would have had this relevant, critical information available to them before

the implantation of the Essure® device. Plaintiffs would not have chosen to have the Essure® device implanted had they been warned by Defendants of the risks and complications posed by the device.

108. Plaintiffs are informed and believe, and based thereon allege, that Plaintiffs detrimentally relied upon representations made in the Essure® brochure and/or video as to the benefits and the risks, as well as relayed by their physicians in reaching their decisions to have the Essure® procedure over tubal ligation and underwent the Essure® procedure without being warned of any risks associated with the Essure devices. After undergoing the Essure procedure, Plaintiffs began to experience one or more of the following symptoms including, but not limited to: severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, back pain, abdominal pain, painful intercourse, headaches, allergic reaction, migration of the device, perforation of device, unwanted pregnancy, severe fatigue, joint pains, allergies, rashes, vertigo, bloating, extreme and unbearable pain, cramping, ectopic or accidental pregnancy, autoimmune response, infections, extreme hair loss, and/or migraine headaches. As a proximate result of Defendants' acts and omissions as alleged herein, Plaintiffs have been catastrophically injured, have been caused severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

109. Had Plaintiffs been properly informed of the true risk that the Essure device can migrate and/or cause persistent pain, bleeding and other injuries similar to those suffered by Plaintiffs, Plaintiffs would not have consented to undergo the Essure® implant as an alternative to standard tubal ligation. Thereafter, Plaintiffs were forced to undergo major surgery as a result of their Essure® implants. In or about July of 2018, Plaintiffs first learned that there may be a causal connection between the injuries they suffered and defects in the Essure device. Prior to 2018, Plaintiffs did not have knowledge of facts that would lead a reasonable, prudent person to inquire or discover Defendants' tortious conduct. Under appropriate application of the discovery rule, Plaintiffs' cases were filed well within all applicable statutory limitations periods.

110. Defendants' misconduct and fraudulent concealment of the relevant facts deprived Plaintiffs and their physicians of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs relied on Defendants' misrepresentations and omissions and therefore could not reasonably have known or become aware of facts that would lead a reasonable,

prudent person to make an inquiry to discover Defendants' tortious conduct. Plaintiffs diligently filed suit once they discovered the actual facts. Defendants' misconduct and fraudulent concealment of the relevant facts, as described infra, tolls any relevant statute of limitations. Under appropriate application of the discovery rule, Plaintiffs' suit is filed well within all applicable statutory limitations periods. Defendants are and were under a continuing duty to monitor and disclose the true character, quality, and nature of Essure®. Due to Defendants' misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendants are estopped from relying on any statute of limitations defense.

VII. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE

111. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

112. Defendants formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, Essure®, including the Essure® devices that were implanted into Plaintiffs.

113. Defendants had a duty under parallel state law, including California law, to exercise reasonable care to provide adequate warning about the risks and dangers of Essure® that were known or knowable to Defendants at the time of distribution.

114. Defendants breached their duty in that they failed to comply with federal regulations by not adequately investigating and/or handling the complaints that they had received related to Essure which led to a failure to properly or timely report adverse events to the FDA.

115. Defendants breached their duty in that they failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendants knew or should have known were associated with Essure® prior to the time of Plaintiffs' implantation.

116. Specifically, Defendants breached these duties and violated federal and state law by, *inter alia*: receiving and failing to warn of or report many of the approximately 32,000 complaints about

Essure® to the FDA or the public and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of migration;

g. instances of chronic/persistent abdominal and pelvic pain/cramping;

h. instances of chronic/persistent irregular vaginal bleeding;

i. instances of the device internally separating or breaking into pieces; and

j. instances of adverse events/reactions requiring surgical device removal.

117. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants failed to disclose and warn of the health hazards and risks associated with Essure®, in violation of state law, including California law, the Essure® CPMA and FDA regulations.

118. In addition, the Essure® CPMA set forth specific reporting requirements - as described above - that obligated Defendants to report:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet any device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

f. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

119. Defendants negligently failed to comply with the above requirements and failed to take necessary action to timely advise users of Essure® of the defects and risks described above. By failing to comply with federal regulations, Defendants failed to properly meet the applicable standard of care under state law, including California law.

120. Defendants had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded.

121. Defendants were cited in 2002, 2003, 2008, 2011 and 2013 by the FDA and CDHP for: failure to report complications it knew were associated with Essure®. These violations were not isolated events, but represented ongoing, systematic, and widespread conduct by Defendants that signified problems with the device starting before Plaintiffs received their Essure® implants and continuing through at least August 2015.

122. Had Defendants timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physicians, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physicians, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

123. In this case, once the medical community and the FDA became aware of the true frequency of adverse events associated with Essure, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

124. Defendants' delay in timely reporting their known complications prevented the Plaintiff and her physicians from having timely information concerning the real-life risks associated with the Essure® device. Had Plaintiffs received timely and adequate information of these serious risks and adverse events, they would not have consented to the Essure® implant.

125. Once the medical community and the FDA became aware of the undisclosed adverse events, physicians began to study Essure® adverse events further and published articles in well-respected medical journals. This information would have been available for review by Plaintiffs and Plaintiffs' physicians.

126. Indeed, if Plaintiffs and Plaintiffs' physicians had been adequately warned of these serious risks and adverse events, they would not have agreed to or used the Essure® implant. As a proximate and legal result of Defendants' failure to comply with its CPMA and FDA post-marketing regulations, Defendants breached their duty of care to Plaintiffs under parallel state law and caused Plaintiffs' past and future suffering, including severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

127. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their CPMA and the FDCA. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence *per se*: 21 C.F.R. § 803.10; 21 C.F.R. §803.17; 21 C.F.R. §803.18; 21 C.F.R. §803.20; 21 C.F.R. §803.22; 21 C.F.R. §803.3; 21 C.F.R. §803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21 C.F.R. §803.22; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. §820.198.

128. Plaintiffs are within the class of persons the statutes and regulations protect, and Plaintiffs' injuries are of the type of harm these statutes and regulations are designed to prevent.

129. Defendants' violations of these statutes and regulations proximately caused Plaintiffs' injuries alleged herein.

130. The conditions of the Essure® CPMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the CPMA. *See* 21 C.F.R. § 814.82(c).

131. As a proximate and legal result of Defendants' failure to exercise reasonable, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

132. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION

STRICT PRODUCTS LIABILITY

133. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

134. Defendants failed to warn Plaintiffs and their physicians of the risk of serious defects and life altering complications described herein rendering the device defective and unreasonably dangerous.

135. Specifically, Defendants failed to:

a. report more than 32,000 complaints about Essure® to the FDA or the public;

b. report Essure®'s nonconformity with its performance specifications; and

c. update Essure®'s labeling or report to the FDA and the medical community their post-market information regarding complaints about Essure®.

136. Plaintiffs' Essure® devices were defective at the time of sale and distribution and at the time it left the possession of Defendants in that Defendants failed to adequately warn of the risks of migration, perforation, penetration, device breakage, removal, chronic abnormal bleeding and pain, autoimmune response, and other injuries involved in the use of Essure®. The accurate rate of occurrence for these and other injuries associated with the use of Essure® were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

137. The Essure® devices were defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendants knew or should have known that the products created a serious risk of migration, perforation, penetration, autoimmune response, and other harm to consumers, and Defendants failed to adequately warn consumers of said risks - including Plaintiffs and/or their healthcare providers - in accordance with state law, including California law.

138. The Essure® devices manufactured and sold by Defendants were defective and unreasonably dangerous due to inadequate warnings and instructions because Defendants knew or should have known that Essure® created, among other things, a higher than expected risk for adverse events, and Defendants failed to adequately warn of those risks, to monitor those risks, report them, and update its labeling regarding such risks when the information became available.

139. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

140. The Essure® devices manufactured, marketed, promoted, and sold by Defendants were expected to, and did, reach Plaintiffs without change in the condition in which they were sold.

141. Despite the fact that Defendants knew or should have known that the use of Essure® was unreasonably dangerous and likely to place users at serious risks to their health, Defendants failed to monitor and warn of the defects, health hazards, and risks associated with Essure®.

142. At the time of sale and distribution, and at the time the devices left the possession of Defendants, Plaintiffs' Essure® devices differed from Defendants' intended result and design specifications.

143. The failures inherent in the Essure® devices were not readily recognizable to the ordinary consumer, including Plaintiffs and/or Plaintiffs' physicians.

144. At all relevant times, Plaintiffs' Essure® devices were prescribed and used as intended by Defendants and in a manner reasonably foreseeable to Defendants.

145. The Essure® devices manufactured, designed, promoted, marketed, and sold by Defendants were expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

146. Defendants knew that the Essure® devices would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

147. At all times relevant to this action, the dangerous propensities of Essure® were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to prescribe and implant Essure® for their patients.

148. Defendants knew that physicians and other healthcare providers began prescribing this product as a safe and effective contraceptive device despite its potential for serious, severe, and permanent side effects.

149. Defendants were required to provide adequate warnings to consumers and the medical community under federal and state law, including California law, but failed to do so in a timely and

responsible manner.

150. Had Defendants timely and adequately reported the adverse events to the FDA, there would have been effective warnings to physicians, including Plaintiffs' physicians, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Plaintiffs and/or Plaintiffs' physicians, regarding the dangers of Essure® that were known or knowable to Defendants at the time of distribution.

151. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a black box warning and Patient Decision Checklist for Essure® that warns of many of the same injuries that Plaintiffs have experienced due to Essure®.

152. Defendants' delay in timely reporting their known complications prevented Plaintiffs and their physicians from having updated information concerning the real-life risks associated with the Essure® device. Had Plaintiffs and their physicians received timely and adequate information of these serious risks and adverse events, they would not have agreed to the Essure® implant, nor would their physicians have recommended use of this product.

153. Essure®, which was manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendants, was a substantial contributing factor in bringing about Plaintiffs' injuries, which would not have occurred but for the use of Essure®.

154. The defective warnings were a substantial contributing factor in bringing about the injuries to Plaintiffs that would not have occurred but for the use of Essure®.

155. As a proximate result and/or substantial factor of the Essure®'s defective condition at the time it was sold, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

156. By reason of the foregoing, Plaintiffs have suffered damages proximately caused by Defendants' wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others,

justifying an award of punitive damages.

157. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION

CONCEALMENT

158. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

159. At all times alleged herein, Defendants had the duty and obligation to truthfully represent the facts concerning Essure® to Plaintiffs and/or their healthcare providers.

160. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages suffered thereby.

161. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suppression of fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact.

162. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by concealing material information concerning Essure®- which Defendants had a duty to disclose, thus misrepresenting the true nature of the device.

163. As described in the forgoing sections, Defendants concealed material facts concerning Essure® from Plaintiffs, their physicians, and other healthcare providers.

164. Specifically, Defendants received and concealed many of the approximately 32,000 complaints about Essure® to the FDA or the public and concealed their knowledge and information regarding complaints about Essure®, including but not limited to:

a. instances of perforation and/or penetration of the fallopian tubes;

b. instances of perforation and/or penetration of the uterus;

c. instances of perforation and/or penetration of the bowel;

d. instances of perforation and/or penetration of the abdominal cavity;

e. instances of perforation and/or penetration of the peritoneal cavity;

f. instances of migration;

g. instances of chronic/persistent abdominal and pelvic pain/cramping;

h. instances of chronic/persistent irregular vaginal bleeding;

i. instances of the device internally separating or breaking into pieces; and

j. instances of adverse events/reactions requiring surgical device removal.

165. Despite the evidence that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants concealed the health hazards and increased risks associated with Essure®, in violation of state law, including California law, the Essure® CPMA and FDA regulations.

166. In addition, in violation of their CPMA, federal law and state law including California law, Defendants concealed:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;

b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;

c. any knowledge or information of Essure®'s failure to meet any device specifications established in the approved CPMA;

d. any changes to the performance of the device;

e. any information from any source that reasonably suggests a device may have caused or contributed to serious injury; and

f. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

167. As described above in the foregoing section, Defendants made affirmative representations to Plaintiffs and/or their physicians before Essure® was implanted in Plaintiffs, while concealing and omitting the material facts including but not limited to those set forth herein. Defendants intended that Plaintiffs, their physicians, and the healthcare industry would rely on their representations, leading to the use of Essure® by Plaintiffs.

168. Defendants intentionally, willfully, and maliciously concealed and/or suppressed material information from Plaintiffs and their physicians with the intent to defraud as alleged herein.

169. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

170. By failing to ensure representations regarding Essure® were truthful, accurate, and not

misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

171. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiffs and their physicians.

172. After the concealed information became known, the FDA mandated the addition of the black box warning and other dramatic changes to the FDA-approved label, including but not limited to an unprecedented patient-decision checklist.

173. Neither Plaintiffs nor their healthcare providers were aware, nor could have been aware, of the concealed and/or suppressed facts. Had Plaintiffs and/or their healthcare providers been aware of those facts, they would not have purchased and used Essure®, and would not have been injured.

174. Plaintiffs and her physicians justifiably relied on and/or were induced by Defendants' misrepresentations and/or concealment. Specifically, Plaintiffs would never have had the Essure® device implanted had they been aware that there were multiple reports of device migration and perforations of human cavities or that there had been over 32,000 complaints regarding Essure®.

175. It is reasonable that Plaintiffs, their physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe and effective because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

176. Defendants had a duty to warn Plaintiffs, their physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiffs and their healthcare providers reasonably relied on Defendants' deception and, Plaintiffs were implanted with Essure® and subsequently sustained injuries and damages as described herein. Defendants' concealment was a substantial contributing factor in causing Plaintiffs' injuries.

177. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs seek punitive damages according to proof.

178. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an

amount to be proven at trial.

179. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

180. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

181. At all times mentioned in this Complaint, Defendants had the duty and obligation to truthfully represent the facts concerning Essure® to Plaintiff and/or her healthcare providers.

182. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages which she thereby suffers.

183. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true.

184. Defendants negligently deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by suggesting untrue facts about their product that they had no reasonable ground for believing to be true.

185. Conceptus' marketing plan not only involved the creation and dissemination of advertisements and marketing materials to the patient; Conceptus also invested heavily in a specialized sales force designed to teach physicians how to market Essure®, generate a referral network, and grow their practice using Essure®. Conceptus' marketing campaigns to physicians included the following:

a. Conceptus' concierge development team and practice program provided all of the necessary Essure® marketing materials to the physician; including posters, pamphlets, promotional letter templates, in-office videos, web-based materials, interactive patient education tools, and phone hold message templates.

b. Conceptus advised both physicians and their staff on Essure® public relations, patient counseling techniques, and how to answer patient questions about Essure®. This included role-playing how to introduce Essure® information to all patients and telephone patient counseling conversation training.

c. Conceptus advised physician staff on reimbursement and other administrative issues related to Essure® with their Essure® Office Management Program.

d. Conceptus helped physicians design their procedure room infrastructure.

e. Conceptus advised physicians how to use external marketing campaigns to draw Essure® patients via radio, TV, DTC, or print.

f. Conceptus advised physicians how to create an extensive public relations plan to include local corporations, plastic surgeons, and other non-OB/GYNs into their referral network for Essure®.

g. Conceptus not only used monetary incentive compensation plans in their own salesforce, they also advised physicians how to integrate staff incentive/motivation plans for increased Essure® sales into their practice.

h. The development team also utilized Conceptus e-newsletters, conference presentations, and multi-day intensive Essure® Summit seminars.

186. Defendants authorized and pioneered a sales plan aimed at physicians that placed profits above patient care. The marketing materials, marketing plans, and sales tactics described above incorporated misrepresentations about the efficacy, risks, and complications of Essure®. These and other misrepresentations also permeated Defendants' DTC marketing and advertising. Whether it was in an advertisement in a magazine, or from counseling received in her doctor's office, the Essure® patient received Defendants' deceptive message about the superiority of Essure®.

187. Defendants directed their willful dissemination of false and misleading information at a time when there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in Defendants' possession.

188. The specific misrepresentations and coinciding facts are identified in Plaintiffs' short form complaints. These statements were false and/or misleading, violating federal law and state law, including California law.

189. Pursuant to 21 U.S. Code § 352 (m), a medical device is rendered misbranded if its advertising is false or misleading in any particular.

190. Additionally, in the case of any restricted device distributed or offered for sale in any State, such a device is rendered misbranded unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device, a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

191. Pursuant to 21 U.S. Code § 321 (n), if an article is alleged to be misbranded because the advertising is misleading, then in determining whether the advertising is misleading, there shall be taken into account (among other things), not only representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the advertising relates under the conditions of use prescribed in the advertising thereof or under such conditions of use as are customary or usual.

192. Defendants' concealment of adverse events, health hazards, and risks associated with Essure® rendered the Essure® device misbranded.

193. Even if Defendants disclosed some information regarding adverse events, their failure to correct inaccuracies and fully disclose material information left any previous disclosure deceptive.

194. By failing to ensure representations regarding Essure® were truthful, accurate, and not

misleading, Defendants have violated the Essure® CPMA, FDA regulations, and parallel state law.

195. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiff and her physicians.

196. Neither Plaintiff nor her healthcare providers were aware of the true risks and complications associated with Essure®. Had Plaintiff and/or her healthcare providers been aware of those facts, she would not have purchased and used Essure®, and Plaintiff would not have been injured as a result.

197. Plaintiff and her physicians justifiably relied on and/or were induced by Defendants' negligent misrepresentations. Specifically, Plaintiff would never have had the Essure® device implanted had she been aware that there were multiple reports of device migration and perforations of human cavities, or that there had been more than 32,000 complaints regarding Essure®.

198. It is reasonable that Plaintiff, her physicians, and the healthcare industry would rely on the statements of Defendants regarding whether Essure® was safe and effective because, as the manufacturer, Defendants were held to the level of knowledge of an expert in the field.

199. Defendants had a duty to warn Plaintiff, her physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the negligent misrepresentations set forth above, Plaintiff and her healthcare providers reasonably relied on Defendants' deception, were implanted with Essure®, and subsequently sustained injuries and damages as described herein. Defendants' negligent misrepresentations were a substantial contributing factor in causing Plaintiff's injuries.

200. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she entitled to compensatory and other damages in an amount to be proven at trial.

201. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiff seeks punitive damages according to proof.

202. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION

FRAUD/ INTENTIONAL MISREPRESENTATION

203. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

204. Defendants violated the Essure® CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in false and misleading advertising of Essure®.

205. Despite the fact that evidence existed that the use of Essure® was dangerous and likely to place users at serious risk to their health, Defendants concealed health hazards and risks associated with Essure®. Instead, Defendants marketed, advertised, and promoted Essure® while failing to warn or otherwise ensure the safety of its users in violation of state law, including California law, the Essure® CPMA and FDA regulations.

206. Conceptus' marketing plan not only involved the creation and dissemination of advertisements and marketing materials to the patient; Conceptus also invested heavily in a specialized sales force designed to teach physicians how to market Essure®, generate a referral network, and grow their practice using Essure®. Conceptus' marketing campaigns to physicians included the following:

a. Conceptus' concierge development team and practice program provided all of the necessary Essure® marketing materials to the physician; including posters, pamphlets, promotional letter templates, in-office videos, web-based materials, interactive patient education tools, and phone hold message templates.

b. Conceptus advised both physicians and their staff on Essure® public relations, patient counseling techniques, and how to answer patient questions about Essure®. This included role-playing how to introduce Essure® information to all patients and telephone patient counseling conversation training.

c. Conceptus advised physician staff on reimbursement and other administrative issues related to Essure® with their Essure® Office Management Program.

d. Conceptus helped physicians design their procedure room infrastructure.

e. Conceptus advised physicians how to use external marketing campaigns to draw Essure® patients via radio, TV, DTC, or print.

f. Conceptus advised physicians how to create an extensive public relations plan to include local corporations, plastic surgeons, and other non-OB/GYNs into their referral network for Essure®.

g. Conceptus not only used monetary incentive compensation plans in their own salesforce, they also advised physicians how to integrate staff incentive/motivation plans for increased Essure® sales into their practice.

h. The development team also utilized Conceptus e-newsletters, conference presentations, and multi-day intensive Essure® Summit seminars.

207. Defendants authorized and pioneered a sales plan aimed at physicians that placed profits above patient care. The marketing materials, marketing plans, and sales tactics described above incorporated misrepresentations about the efficacy, risks, and complications of Essure®. These and other misrepresentations also permeated Defendants' DTC marketing and advertising. Whether it was in an advertisement in a magazine, or from counseling received in her doctor's office, the Essure® patient received Defendants' deceptive message about the superiority of Essure®.

208. Defendants directed their willful dissemination of false and misleading information at a time when there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in Defendants' possession.

209. Defendants' conduct not only violated its federal regulatory duties and its duties under state law, including California law, but also failed to provide information that was necessary for the medical and scientific community to protect each patient's interest. Because the Defendants failed to timely, completely, or accurately disclose their knowledge of the risks and complications associated with the Essure® device, the public's knowledge of the risks associated with the Essure® device were seriously hampered and delayed. This delay of information endangered patient safety, including Plaintiff's safety.

210. At all times mentioned in this Complaint, Defendants had the duty and obligation to disclose to Plaintiff and/or her healthcare providers, the true facts concerning Essure®.

211. California Civil Code § 1709 provides that one who willfully deceives another with intent to induce her to alter her position to her injury or risk is liable for any damages which she thereby suffers.

212. California Civil Code § 1710 provides, in part, that a deceit, within the meaning of § 1709, is the suggestion, as a fact, of that which is not true, by one who does not believe it to be true.

213. Defendants willfully deceived Plaintiffs, their healthcare providers, the medical community, and the public in general, by suggesting untrue facts about their product that they knew to be false.

214. The specific misrepresentations and coinciding facts are identified in Plaintiffs' short form complaints. These statements were false and/or misleading, violating federal law and state law, including California law.

215. At the time Essure® was manufactured, distributed, and sold to Plaintiffs, Defendants were in a unique position of knowledge concerning the safety and effectiveness of Essure®, and thereby held a position of superiority over Plaintiffs and their physicians.

216. Neither Plaintiffs nor their healthcare providers were aware of the true risks and complications associated with Essure®. Had Plaintiffs and/or their healthcare providers been aware of those facts, they would not have purchased and used Essure®, and Plaintiff would not have been injured as a result.

217. Plaintiffs and their physicians justifiably relied on and/or were induced by Defendants' intentional misrepresentations. Specifically, Plaintiffs would never have had the Essure® device implanted had they been aware that there were multiple reports of device migration and perforations of human cavities or that there had been more than 32,000 complaints regarding Essure®.

218. Plaintiffs, their physicians, and the healthcare industry reasonably relied upon Defendants' statements because, as the manufacturer, Defendants were held to the level of knowledge of an expert.

219. Defendants had a duty to warn Plaintiffs, their physicians, and the general public about the potential risks and complications associated with Essure® in a timely manner. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff and her healthcare providers reasonably relied on Defendants' deception, were implanted with Essure®, and subsequently sustained

injuries and damages as described herein. Defendants' deception was a substantial contributing factor in causing Plaintiffs' injuries.

220. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which they are entitled to compensatory and other damages in an amount to be proven at trial.

221. As a result of the foregoing fraudulent and deceitful conduct by Defendants, Plaintiffs seek punitive damages according to proof.

222. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

223. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

224. The specific express warranties communicated to Plaintiffs and coinciding facts are identified in Plaintiffs' short form complaints.

225. Defendants breached those warranties because the Essure® devices implanted into Plaintiffs and Plaintiffs' experience with Essure® did not conform to the express warranties created by Defendants and instead Plaintiffs suffered severe physical injuries, mental anguish, economic loss, and other injuries.

226. Defendants' express warranties were specifically and expressly communicated to Plaintiffs in such a manner that Plaintiffs understood and accepted them.

227. Defendants' affirmations of fact or promise and descriptions of Essure® created a basis of the bargain for Plaintiffs and/or their physicians.

228. At the time of making of the express warranties, Defendants had knowledge of the purpose for which Essure® was to be used and warranted the device to be in all respects fit, safe, effective, and proper for such purpose. Essure® was unaccompanied by adequate warnings of its dangerous propensities and lack of effectiveness that were either known or knowable to Defendants at the time of distribution and sale.

229. Defendants' breaches of their express warranties under state law parallel their violations of federal law; the Essure® CPMA specifically mandates, and state law, including California law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

230. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendants, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

231. Plaintiffs and/or their healthcare providers reasonably relied upon said express warranties, in choosing to use Essure®.

232. As soon as the true nature of Essure® and the fact that the warranties and representations were false was ascertained, Defendants were on notice of the breach of said warranties.

233. As a proximate result of Defendants' warranties and Plaintiff's and Plaintiff's physician's reliance on same, Plaintiff has suffered and continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

234. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

SEVENTH CAUSE OF ACTION

MANUFACTURING DEFECT

235. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

236. After Essure® was approved for sale by the FDA in 2002, Defendants had a duty under state law, including California law, to exercise reasonable care in the manufacture of Essure® and to manufacture the Essure® devices consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval.

237. Defendants negligently failed to comply with FDA regulations and specifications for the Essure© device and were cited by the FDA for, *inter alia*:

a. failing to conform to the approved Essure® design specifications;

b. failing to use components that were fully certified;

c. failing to use pre-sterile and post-sterile cages;

d. manufacturing Essure® at an unlicensed facility;

e. failing to analyze or identify existing potential causes of non-conforming product and other quality problems;

f. failing to track non-conforming product;

g. failing to follow procedures used to control products which did not conform to specifications;

h. failing to have a complete Design Failure Analysis; and

i. failing to document CAPA activities for a supplier correction action.

238. Defendants negligently failed to comply with FDA regulations and its parallel duties under state law, including California law, thereby jeopardizing the health of patients.

239. These violations were not isolated events, but represented ongoing, systematic, and widespread conduct by Defendants that signified problems with the device starting before Plaintiffs received their Essure® implants and continuing through at least August 2015.

240. Conceptus' knowledge that its Essure devices did not comply with regulatory requirements and the PMA specification can be seen throughout its filings with the SEC beginning in 2005 and therein after annually for nearly a decade. Conceptus admits its dependence on, and concerns that, it's third-party sub-contractors may not comply with FDA and other health authority regulations:

a. "We have limited experience manufacturing our product in the volumes that will be necessary to achieve significant commercial sales. To achieve our production volume objectives, we decided to outsource our manufacturing activity to a third-party contract manufacturer..."

b. "We transitioned almost all of our internal manufacturing operations to Accellent by the end of 2004 to manufacture the components and assemble our product. Similarly, we have subcontracted with Sterigenics International to handle the sterilization of our products. **We cannot assure you that we, our contract manufacturer, component suppliers or other subcontractors will be able to maintain compliance with all**

regulatory requirements." (Emphasis added).

c. "Furthermore, **we cannot assure you** that if we find it necessary to engage new manufacturers, suppliers or subcontractors to satisfy our business requirements that we will be able to locate **new manufacturers, suppliers or contractors who are in compliance with regulatory requirements**." (Emphasis added).

d. "We depend on our contract manufacturer to supply our commercial product requirements and we may experience disruption in supply if they are not in compliance with FDA and other health authority regulations …"

e. "If Accellent does not comply with FDA and other health authority regulations or encounters manufacturing difficulties, this could negatively impact sales of the Essure system."

f. "We may not maintain regulatory approvals for the Essure system, our only product…"

g. "If we or Accellent, our third-party manufacturer, do not comply with applicable regulatory requirements, we may be subject to warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of approvals and criminal prosecution, among other penalties."

h. "Our suppliers may encounter problems during manufacturing due to a variety of reasons, including **failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunctions, labor shortages or environmental factors.**" (Emphasis added).

241. The specific facts concerning which Essure® lot Plaintiffs' devices were from, the defects determined to be present in those lots, and the defects present in Plaintiffs' devices are alleged in Plaintiffs' short form complaints.

242. Upon information and belief, the devices implanted into Plaintiffs were negligently manufacturered and contained defects that rendered the device noncompliant with FDA regulations and specifications.

243. The devices are not intended to deform, crack, fracture, or break before, during, or any time

after implantation. Defendants received notices of each of these types of failure modes, yet failed to, among other things: (1) promptly investigate the cause of the device failure modes; (2) notify the public that they had occurred; or (3) report the adverse events and the device failure modes to the FDA.

244. As a proximate and legal result of Defendants' failure to manufacture the Essure® devices consistent with FDA specifications, the Essure® CPMA, and/or conditions of approval, Plaintiffs have suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages in an amount to be proved at trial.

245. WHEREFORE, Plaintiffs pray for judgment against Defendants as hereinafter set forth.

VIII. REQUEST FOR PUNITIVE DAMAGES

246. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

247. At all times relevant herein, Defendants:

a. knew or should have known that Essure® was dangerous, defective, and ineffective;

b. concealed the dangers and health risks from Plaintiffs, physicians, other medical providers, the FDA, and the public at large;

c. attempted to misrepresent and did knowingly make misrepresentations to Plaintiffs, their physicians, hospitals, other medical providers, and the public in general, as previously stated herein, as to the safety and efficacy of Essure®; and

d. with full knowledge of the health risks associated with Essure® and without adequate warnings of the same, manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, promoted, marketed, advertised, distributed, and sold Essure® for use.

248. Defendants, by and through its officers, directors, managing agents, authorized sales representatives, employees, and/or other agents who engaged in malicious, fraudulent, and oppressive conduct towards Plaintiffs and the public, acted with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiffs and the general public.

249. Defendants' knowingly withheld material information from the medical community and the public, including Plaintiffs, concerning the safety of Essure®. Defendants' conduct was willful, wanton, and undertaken with a disregard for Plaintiffs' rights.

250. Notwithstanding the foregoing, Defendants continued to market Essure® to consumers, including Plaintiff herein, without disclosing the risks.

251. Defendants knew of Essure®'s lack of warnings, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell Essure® without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Essure®.

252. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using Essure® against its benefits.

253. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiffs suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiffs have become liable.

254. Defendants are liable jointly and/or severally for all general, special, and compensatory damages to which Plaintiffs are entitled by law. Plaintiffs seek actual and punitive damages from Defendants and allege that the conduct of Defendants was committed with knowing, conscious, careless, reckless, willful, wanton, deliberate, and grossly negligent disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

255. WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory, and punitive damages, together with interest, costs of suit, attorney's fees, and all such other relief as the Court deems appropriate pursuant to common law and statutory law.

IX. AGENCY, ALTER EGO, JOINT VENTURE, AND CONSPIRACY

256. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

257. At all times herein mentioned, Defendants were fully informed of the actions of their

agents, representatives, contractors, and/or employees, and thereafter, no officer, director or managing agent of Defendants repudiated those actions. The failure to repudiate constituted adoption and approval of said actions, and all Defendants and each of them thereby ratified those actions.

258. At all times mentioned herein, there existed (and still exists) a unity of interest between certain Defendants and other Defendants such that any individuality and separateness between the Defendants has ceased, and these Defendants are the alter egos of the other certain Defendants and exerted control over those Defendants. Defendant Bayer controlled its wholly owned subsidiaries to such a degree and in such a manner as to render them mere business units and to make them merely an agency, instrumentality, adjunct, or its alter ego. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege, sanction a fraud, and/or promote injustice.

259. Each of the Defendants herein expressly or impliedly agreed to work with and assist each other Defendant and unnamed parties toward the common purpose of promoting, recommending, and selling Essure® and toward the common interest of pecuniary gain.

260. Each of the Defendants performed the acts and omissions described herein in concert with the other Defendants and/or pursuant to a common design with the other Defendants.

261. Each of the Defendants knew the acts and omissions of the other Defendants herein constituted a breach of duty, and yet, each Defendant provided each other Defendant substantial assistance and/or encouragement.

262. Each of the Defendants provided substantial assistance to the other Defendants in accomplishing the intentional and tortious conduct described herein, and each Defendants' conduct, even when separately considered, constitutes a breach of duties owed to Plaintiff.

263. At all times herein mentioned, each of the Defendants was engaged in the business of and/or was a successor in interest to and/or affiliated with/associated with/indistinguishable from entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling Essure® device for use by Plaintiffs and their physicians. As such, each of the Defendants is individually, as well as jointly and severally, liable to the Plaintiffs

for their damages.

264. The conduct of Defendants caused Plaintiff harm as described herein. Plaintiffs' harm is not in any way attributable to any fault of Plaintiffs or any third party or instrumentality. Uncertainty may exist regarding which Defendant and/or combination of Defendants caused Plaintiff's harm. Defendants possess superior knowledge and information regarding which Defendant and/or combination of Defendants caused Plaintiffs' injuries. Thus, the burden of proof is upon each Defendant to prove the Defendant did not cause Plaintiff's harm as described herein.

265. Thus, the burden of proof should be upon each Defendant to prove that it has not caused the harms suffered by Plaintiffs.

266. Due to the above, each cause of action is asserted against each Defendant herein, jointly and severally, even if each and every Defendant is not specifically identified as to each and every count.

X. EQUITABLE TOLLING/FRAUDULENT CONCEALMENT

267. Plaintiffs repeat and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

268. Defendants' failure to report, document, or follow up on the known adverse event complaints, and concealment of adverse events, known defects, serious increased risks, dangers, and complications, constitute fraudulent concealment that equitably tolls any proffered statute of limitation that may otherwise bar the recovery sought by Plaintiff herein.

269. Defendants are estopped from relying on any statute of limitations defense because they continued to refute and deny reports and studies questioning the safety of Essure®, actively and intentionally concealed defects, suppressed reports and adverse information, failed to satisfy FDA and PMA requirements, failed to satisfy FDA and PMA notification requirements, and failed to disclose known dangerous defects and serious increased risks and complications to physicians and Plaintiffs.

270. Instead, Defendant represented that Essure® was safer, more effective and the best alternative for permanent female sterilization despite their knowledge to the contrary.

271. At all relevant times, Defendants were under a continuing duty under federal law, the PMA and parallel state laws to disclose the true character, quality, and nature of the increased risks, adverse events, and dangers associated with Essure®.

272. As a result of Defendants' concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

273. Defendants furthered their fraudulent concealment through acts and omissions, including misrepresenting known dangers and/or defects in Essure® and/or arising out of the use of Essure® and a continued and systematic failure to disclose and/or cover up such information from/to Plaintiffs, Plaintiffs' physicians, and the public.

274. Defendants' acts and omissions, before, during, and/or after the act causing Plaintiffs' injury prevented Plaintiffs and/or their physicians from discovering the injury or cause thereof until recently.

275. Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, reckless, and without regard to the consequences or the rights and safety of the Plaintiffs.

XI. RELIEF REQUESTED

WHEREFORE Plaintiffs pray for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of Plaintiffs, as follows:

1. compensatory damages, including, but not limited to, pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial;

2. economic damages in the form of medical expenses, out of pocket expenses, lost earnings and earning capacity, and other economic damages in an amount to be determine at trial;

3. an award of attorneys' fees and costs;

4. prejudgment interest;

5. post-judgment interest;

6. punitive or exemplary damages according to proof; and

7. for such other and further relief as this Court may deem just and proper.

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XII. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all claims.

Respectfully submitted,

Dated: October 25, 2018

ROBINSON CALCAGNIE, INC.

By: _____

Mark P. Robinson, Jr. Esq.
Karen L. Karavatos, Esq.
Cynthia Garber, Esq.

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Mark P. Robinson, Jr. SBN 0054426
ROBINSON CALCAGNIE, INC.
19 Corporate Plaza Drive
Newport Beach, CA 92660
TELEPHONE NO.: 949-720-1288 FAX NO.: 949-720-1292
ATTORNEY FOR (Name): Plaintiffs

FOR 21083625

FILED
ALAMEDA COUNTY
OCT 26 2018
CLERK OF THE SUPERIOR COURT
By Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda
STREET ADDRESS: 1225 Fallon Street
MAILING ADDRESS:
CITY AND ZIP CODE: Oakland, CA 94612
BRANCH NAME: Rene C. Davidson Courthouse

CASE NAME:
ARTINIAN, et al v. BAYER CORP., et al

CASE NUMBER: RG 18926258

JUDGE:
DEPT:

CIVIL CASE COVER SHEET

☑ **Unlimited** (Amount demanded exceeds $25,000) ☐ **Limited** (Amount demanded is $25,000 or less)

Complex Case Designation

☐ **Counter** ☐ **Joinder**

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort
- ☐ Auto (22)
- ☐ Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- ☐ Asbestos (04)
- ☑ Product liability (24)
- ☐ Medical malpractice (45)
- ☐ Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- ☐ Business tort/unfair business practice (07)
- ☐ Civil rights (08)
- ☐ Defamation (13)
- ☐ Fraud (16)
- ☐ Intellectual property (19)
- ☐ Professional negligence (25)
- ☐ Other non-PI/PD/WD tort (35)

Employment
- ☐ Wrongful termination (36)
- ☐ Other employment (15)

Contract
- ☐ Breach of contract/warranty (06)
- ☐ Rule 3.740 collections (09)
- ☐ Other collections (09)
- ☐ Insurance coverage (18)
- ☐ Other contract (37)

Real Property
- ☐ Eminent domain/Inverse condemnation (14)
- ☐ Wrongful eviction (33)
- ☐ Other real property (26)

Unlawful Detainer
- ☐ Commercial (31)
- ☐ Residential (32)
- ☐ Drugs (38)

Judicial Review
- ☐ Asset forfeiture (05)
- ☐ Petition re: arbitration award (11)
- ☐ Writ of mandate (02)
- ☐ Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- ☐ Antitrust/Trade regulation (03)
- ☐ Construction defect (10)
- ☐ Mass tort (40)
- ☐ Securities litigation (28)
- ☐ Environmental/Toxic tort (30)
- ☐ Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- ☐ Enforcement of judgment (20)

Miscellaneous Civil Complaint
- ☐ RICO (27)
- ☐ Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
- ☐ Partnership and corporate governance (21)
- ☐ Other petition *(not specified above)* (43)

2. This case ☑ is ☐ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. ☑ Large number of separately represented parties
   b. ☑ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. ☑ Substantial amount of documentary evidence
   d. ☑ Large number of witnesses
   e. ☑ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. ☑ Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. ☑ monetary b. ☑ nonmonetary; declaratory or injunctive relief c. ☑ punitive
4. Number of causes of action *(specify)*: 7
5. This case ☐ is ☑ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: October 25, 2018
Karen L. Karavatos
(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on **all** other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

INSTRU ONS ON HOW TO COMPLETE THE CO SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
  - Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

F. ADDENDUM TO CIVIL CASE COVER SH *Unified Rules of the Superior C ... f California, County of Alameda*

Short Title: ARTINIAN, et al v. BAYER CORP., et al **Case Number:**

CIVIL CASE COVER SHEET ADDENDUM

THIS FORM IS REQUIRED IN ALL NEW UNLIMITED CIVIL CASE FILINGS IN THE SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA

[ ] Hayward Hall of Justice (447)

[X] Oakland, Rene C. Davidson Alameda County Courthouse (446) [ ] Pleasanton, Gale-Schenone Hall of Justice (448)

Civil Case Cover Sheet Category	Civil Case Cover Sheet Case Type	Alameda County Case Type (check only one)
Auto Tort	Auto tort (22)	[ ] 34 Auto tort (G) **Is this an uninsured motorist case? [ ] yes [ ] no**
Other PI /PD / WD Tort	Asbestos (04)	[ ] 75 Asbestos (D)
	Product liability (24)	[X] 89 Product liability (not asbestos or toxic tort/environmental) (G)
	Medical malpractice (45)	[ ] 97 Medical malpractice (G)
	Other PI/PD/WD tort (23)	[ ] 33 Other PI/PD/WD tort (G)
Non - PI /PD / WD Tort	Bus tort / unfair bus. practice (07)	[ ] 79 Bus tort / unfair bus. practice (G)
	Civil rights (08)	[ ] 80 Civil rights (G)
	Defamation (13)	[ ] 84 Defamation (G)
	Fraud (16)	[ ] 24 Fraud (G)
	Intellectual property (19)	[ ] 87 Intellectual property (G)
	Professional negligence (25)	[ ] 59 Professional negligence - non-medical (G)
	Other non-PI/PD/WD tort (35)	[ ] 03 Other non-PI/PD/WD tort (G)
Employment	Wrongful termination (36)	[ ] 38 Wrongful termination (G)
	Other employment (15)	[ ] 85 Other employment (G)
		[ ] 53 Labor comm award confirmation
		[ ] 54 Notice of appeal - L.C.A.
Contract	Breach contract / Wrnty (06)	[ ] 04 Breach contract / Wrnty (G)
	Collections (09)	[ ] 81 Collections (G)
	Insurance coverage (18)	[ ] 86 Ins. coverage - non-complex (G)
	Other contract (37)	[ ] 98 Other contract (G)
Real Property	Eminent domain / Inv Cdm (14)	[ ] 18 Eminent domain / Inv Cdm (G)
	Wrongful eviction (33)	[ ] 17 Wrongful eviction (G)
	Other real property (26)	[ ] 36 Other real property (G)
Unlawful Detainer	Commercial (31)	[ ] 94 Unlawful Detainer - commercial **Is the deft. in possession**
	Residential (32)	[ ] 47 Unlawful Detainer - residential **of the property?**
	Drugs (38)	[ ] 21 Unlawful detainer - drugs **[ ] Yes [ ] No**
Judicial Review	Asset forfeiture (05)	[ ] 41 Asset forfeiture
	Petition re: arbitration award (11)	[ ] 62 Pet. re: arbitration award
	Writ of Mandate (02)	[ ] 49 Writ of mandate
		Is this a CEQA action (Publ.Res.Code section 21000 et seq) [ ] Yes [ ] No
	Other judicial review (39)	[ ] 64 Other judicial review
Provisionally Complex	Antitrust / Trade regulation (03)	[ ] 77 Antitrust / Trade regulation
	Construction defect (10)	[ ] 82 Construction defect
	Claims involving mass tort (40)	[X] 78 Claims involving mass tort
	Securities litigation (28)	[ ] 91 Securities litigation
	Toxic tort / Environmental (30)	[ ] 93 Toxic tort / Environmental
	Ins covrg from cmplx case type (41)	[ ] 95 Ins covrg from complex case type
Enforcement of Judgment	Enforcement of judgment (20)	[ ] 19 Enforcement of judgment
		[ ] 08 Confession of judgment
Misc Complaint	RICO (27)	[ ] 90 RICO (G)
	Partnership / Corp. governance (21)	[ ] 88 Partnership / Corp. governance (G)
	Other complaint (42)	[ ] 68 All other complaints (G)
Misc. Civil Petition	Other petition (43)	[ ] 06 Change of name
		[ ] 69 Other petition

Robinson Calcagnie Robinson Shapiro Davis, Inc.
Attn: Robinson Jr, Mark P
19 Corporate Plaza Drive
Newport Beach, CA 92660

Bayer Corp

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Artinian Plaintiff/Petitioner(s) VS. Bayer Corp Defendant/Respondent(s) (Abbreviated Title)	No. RG18926258 NOTICE OF HEARING

To each party or to the attorney(s) of record for each party herein:

Notice is hereby given that the above-entitled action has been set for:

Complex Determination Hearing
Case Management Conference

You are hereby notified to appear at the following Court location on the date and time noted below:

Complex Determination Hearing:
DATE: 01/15/2019 TIME: 03:00 PM DEPARTMENT: 23
LOCATION: Administration Building, Fourth Floor
1221 Oak Street, Oakland

Case Management Conference:
DATE: 03/05/2019 TIME: 03:00 PM DEPARTMENT: 23
LOCATION: Administration Building, Fourth Floor
1221 Oak Street, Oakland

Pursuant to California Rules of Court, Rule 3.400 et seq. and Local Rule 3.250 (Unified Rules of the Superior Court, County of Alameda), the above-entitled matter is set for a Complex Litigation Determination Hearing and Initial Complex Case Management Conference.

Department 23 issues tentative rulings on DomainWeb (www.alameda.courts.ca.gov/domainweb). For parties lacking access to DomainWeb, the tentative ruling must be obtained from the clerk at (510) 267-6939. Please consult Rule 3.30(c) of the Unified Rules of the Superior Court, County of Alameda, concerning the tentative ruling procedures for Department 23.

Counsel or party requesting complex litigation designation is ordered to serve a copy of this notice on all parties omitted from this notice or brought into the action after this notice was mailed.

All counsel of record and any unrepresented parties are ordered to attend this Initial Complex Case Management Conference unless otherwise notified by the Court.

Failure to appear, comply with local rules or provide a Case Management Conference statement may result in sanctions. Case Management Statements may be filed by E-Delivery, by submitting directly to the E-Delivery Fax Number (510) 267-5732. No fee is charged for this service. For further information, go to **Direct Calendar Departments** at

http://apps.alameda.courts.ca.gov/domainweb.

All motions in this matter to be heard prior to Complex Litigation Determination Hearing must be scheduled for hearing in Department 23.

If the information contained in this notice requires change or clarification, please contact the courtroom clerk for Department 23 by e-mail at Dept.23@alameda.courts.ca.gov or by phone at (510) 267-6939.

TELEPHONIC COURT APPEARANCES at Case Management Conferences may be available by contacting CourtCall, an independent vendor, at least 3 business days prior to the scheduled conference. Parties can make arrangements by calling (888) 882-6878, or faxing a service request form to (888) 883-2946. This service is subject to charges by the vendor.

Dated: 10/26/2018

Chad Finke Executive Officer / Clerk of the Superior Court

By Digital

Deputy Clerk

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as shown hereon and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 10/29/2018.

By Digital

Deputy Clerk

21091396

Attorney or Party without Attorney: ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs	*For Court Use Only* **FILED** **ALAMEDA COUNTY** NOV 09 2018 CLERK OF THE SUPERIOR COURT By _____ Deputy
Ref. No. or File No.: ARTINIAN, ET AL.-34583	
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA	
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.	

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons, Complaint for Damages; Demand for Jury Trial

3. *a. Party served:* BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation doing business in California
   b. Person served: BECKY DEGEORGE, CSC LAWYERS INCORPORATING SERVICE, REGISTERED AGENT

4. *Address where the party was served:* 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive process for the party (1) on: Mon, Nov 05 2018 at: 10:18 AM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other) :**

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation doing business in California under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership)	[ ] 416.90 (authorized person)
[ ] 416.50 (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Attorney or Party without Attorney: ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs				*For Court Use Only*
	Ref. No. or File No.: ARTINIAN, ET AL.-34583			
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA				
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.				
PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Michael Morris
   b. Address: **FIRST LEGAL**
      600 W. Santa Ana Blvd., Ste. 101
      SANTA ANA, CA 92701
   c. Telephone number: (714) 541-1110
   d. **The fee** for service was: $22.00
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 2102-33
         (iii) County: Sacramento

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

11/06/2018 *(Date)*

(Signature)

Attorney or Party without Attorney: ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs *Ref. No. or File No.:* ARTINIAN, ET AL.-34583	*For Court Use Only* FILED ALAMEDA COUNTY NOV 09 2018 CLERK OF THE SUPERIOR COURT By _____ Deputy
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA	
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.	

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons, Complaint for Damages; Demand for Jury Trial

3. *a. Party served:* BAYER CORP., an Indiana corporation doing business in California
   b. Person served: BECKY DEGEORGE, CSC LAWYERS INCORPORATING SERVICE, REGISTERED AGENT

4. *Address where the party was served:* 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive process for the party (1) on: Mon, Nov 05 2018 at: 10:18 AM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other) :**

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: BAYER CORP., an Indiana corporation doing business in California under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership)	[ ] 416.90 (authorized person)
[ ] 416.50 (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Attorney or Party without Attorney:		For Court Use Only
ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs	*Ref. No. or File No.:* ARTINIAN, ET AL.-34583	
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA		
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.		

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Michael Morris
   b. Address: FIRST LEGAL
      600 W. Santa Ana Blvd., Ste. 101
      SANTA ANA, CA 92701
   c. Telephone number: (714) 541-1110
   d. **The fee** for service was: $22.00
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 2102-33
         (iii) County: Sacramento

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

11/06/2018 *(Date)*

(Signature)

Attorney or Party without Attorney: ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs *Ref. No. or File No.:* ARTINIAN, ET AL.-34583	*For Court Use Only* FILED ALAMEDA COUNTY NOV 09 2018 CLERK OF THE SUPERIOR COURT By _____ Deputy
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA	
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.	

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons, Complaint for Damages; Demand for Jury Trial

3. a. *Party served:* BAYER HEALTHCARE LLC, a Delaware company doing business in California
   b. *Person served:* BECKY DEGEORGE, CSC LAWYERS INCORPORATING SERVICE, REGISTERED AGENT

4. *Address where the party was served:* 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive process for the party (1) on: Mon, Nov 05 2018 at: 10:18 AM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other)** :

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: BAYER HEALTHCARE LLC, a Delaware company doing business in California under the following Code of Civil Procedure section:

[ ] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership)	[ ] 416.90 (authorized person)
[ ] 416.50 (public entity)	[ ] 415.46 (occupant)
[X] other: Limited Liability Company	

Attorney or Party without Attorney:	For Court Use Only
ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 Telephone No: (949) 720-1288 Attorney For: Plaintiffs	Ref. No. or File No.: ARTINIAN, ET AL.-34583
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA	
Plaintiff: KATIE ARTINIAN, an individual; et al. Defendant: BAYER CORP., an Indiana corporation doing business in California; et al.	

PROOF OF SERVICE SUMMONS	Hearing Date:	Time:	Dept/Div:	Case Number: RG18926258

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Michael Morris
   b. Address: **FIRST LEGAL**
      600 W. Santa Ana Blvd., Ste. 101
      SANTA ANA, CA 92701
   c. Telephone number: (714) 541-1110
   d. **The fee** for service was: $22.00
   e. I am:
      (1) [ ] not a registered California process server.
      (2) [ ] exempt from registration under Business and Professions Code section 22350(b).
      (3) [X] a registered California process server:
         (i) [ ] owner [ ] employee [X] independent contractor
         (ii) Registration No: 2102-33
         (iii) County: Sacramento

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

11/06/2018 (Date) (Signature)

Attorney or Party without Attorney:
ROBINSON CALCAGNIE, INC.
Mark P. Robinson, Jr., Esq. (SBN 054426)
19 CORPORATE PLAZA DRIVE
NEWPORT BEACH, CA 92660
Telephone No: (949) 720-1288
Attorney For: Plaintiffs

Ref. No. or File No.:
ARTINIAN, ET AL.-34583

For Court Use Only

FILED
ALAMEDA COUNTY
NOV 09 2018
CLERK OF THE SUPERIOR COURT
By Deputy

Insert name of Court, and Judicial District and Branch Court:
SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA

Plaintiff: KATIE ARTINIAN, an individual; et al.
Defendant: BAYER CORP., an Indiana corporation doing business in California; et al.

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

1. *At the time of service I was at least 18 years of age and not a party to this action.*

2. I served copies of the Summons, Complaint for Damages; Demand for Jury Trial

3. a. *Party served:* CONCEPTUS, INC., a Delaware corporation with its principal place of business in California, now known as BAYER ESSURE, INC.
   b. *Person served:* BECKY DEGEORGE, CSC LAWYERS INCORPORATING SERVICE, REGISTERED AGENT

4. *Address where the party was served:* 2710 Gateway Oaks Drive, Suite 150N, Sacramento, CA 95833

5. *I served the party:*
   a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive process for the party (1) on: Mon, Nov 05 2018 at: 10:18 AM
   (1) [X] **(business)**
   (2) [ ] **(home)**
   (3) [ ] **(other) :**

6. The "Notice to the Person Served" (on the summons) was completed as follows:
   a. [ ] as an individual defendant.
   b. [ ] as the person sued under the fictitious name of *(specify)*:
   c. [ ] as occupant.
   d. [X] On behalf of *(specify)*: CONCEPTUS, INC., a Delaware corporation with its principal place of business in California, now known as BAYER ESSURE, INC.
   under the following Code of Civil Procedure section:

[X] 416.10 (corporation)	[ ] 415.95 (business organization, form unknown)
[ ] 416.20 (defunct corporation)	[ ] 416.60 (minor)
[ ] 416.30 (joint stock company/association)	[ ] 416.70 (ward or conservatee)
[ ] 416.40 (association or partnership)	[ ] 416.90 (authorized person)
[ ] 416.50 (public entity)	[ ] 415.46 (occupant)
[ ] other:	

Attorney or Party without Attorney:		For Court Use Only
ROBINSON CALCAGNIE, INC. Mark P. Robinson, Jr., Esq. (SBN 054426) 19 CORPORATE PLAZA DRIVE NEWPORT BEACH, CA 92660 *Telephone No:* (949) 720-1288 *Attorney For:* Plaintiffs	*Ref. No. or File No.:* ARTINIAN, ET AL.-34583	
Insert name of Court, and Judicial District and Branch Court: SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF ALAMEDA		
Plaintiff: KATIE ARTINIAN, an individual; et al. *Defendant:* BAYER CORP., an Indiana corporation doing business in California; et al.		

PROOF OF SERVICE SUMMONS	*Hearing Date:*	*Time:*	*Dept/Div:*	*Case Number:* RG18926258

Recoverable cost Per CCP 1033.5(a)(4)(B)

7. **Person who served papers**
   a. Name: Michael Morris
   b. Address: **FIRST LEGAL**
      600 W. Santa Ana Blvd., Ste. 101
      SANTA ANA, CA 92701
   c. Telephone number: (714) 541-1110
   d. **The fee** for service was: $104.50
   e. I am:
      (1) ☐ not a registered California process server.
      (2) ☐ exempt from registration under Business and Professions Code section 22350(b).
      (3) ☒ a registered California process server:
         (i) ☐ owner ☐ employee ☒ independent contractor
         (ii) Registration No: 2102-33
         (iii) County: Sacramento

8. ***I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.***

11/06/2018 *(Date)*

(Signature)